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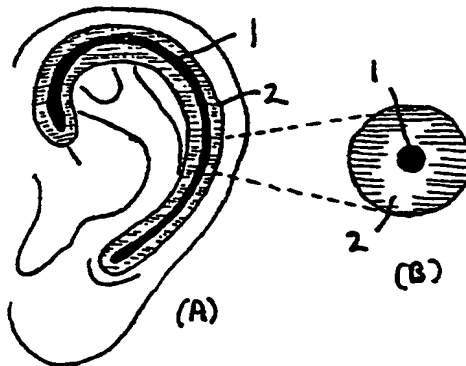
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(58) continued overleaf

(54) Ear splint

(57) The splint comprises a wire core (1) enclosed in a dermatologically acceptable cover (2). It is formed into a desired shape and fitted to the auricle of the ear within 3-6 months of birth to assist in holding the ear in a desired position and/or shape. Foam protector means may be provided for fitting around the ear. For older patients, a topical chemotherapeutic agent may also be applied to the ear to reduce its rigidity.

FIG.2.



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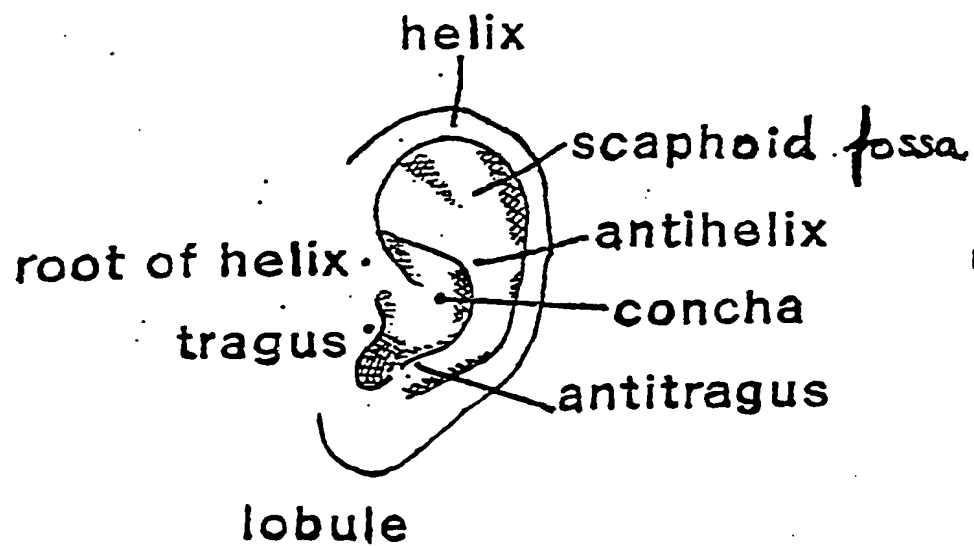


FIG. 1.

FIG. 2.

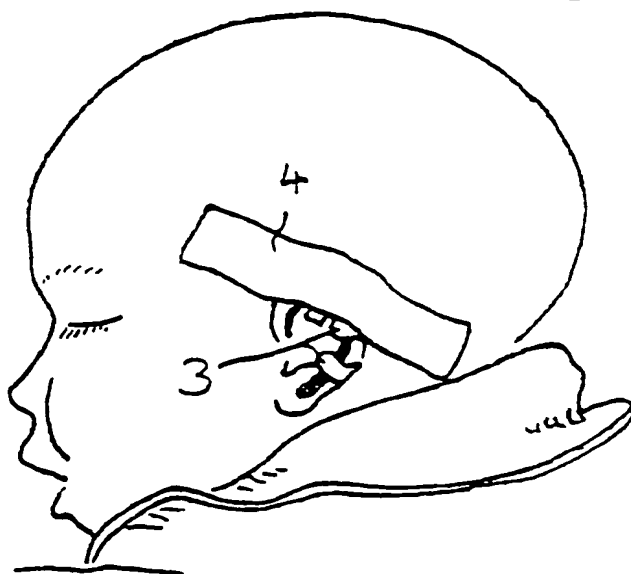
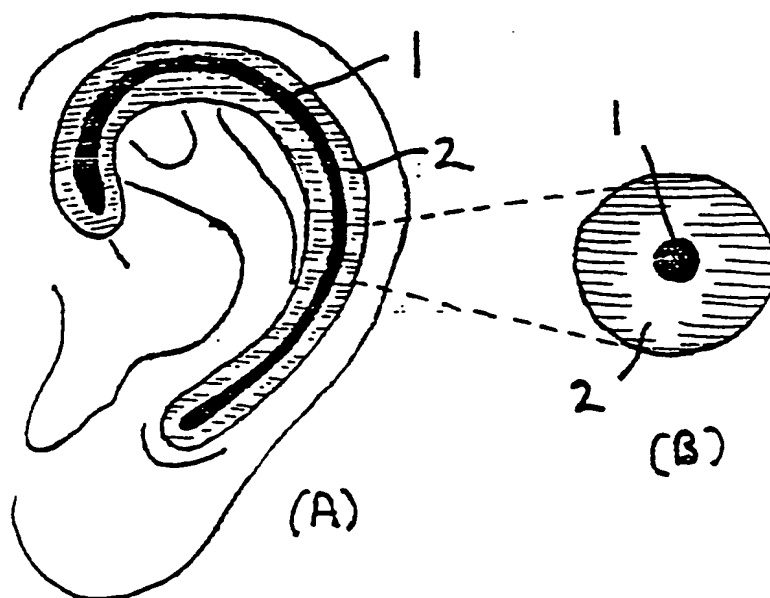


FIG. 3.

EAR SPLINT

This invention relates to an ear splint for use in holding an ear in a desired position or shape.

A number of children are born with funny-looking ears - ears with abnormal kinks or folds in the rim or the centre. Even more children develop prominent or bat ears. Many of these children adjust readily to minor variants from normal, but for others, the psychological effects of an ear deformity are considerable.

The conventional solution to such a dilemma is surgery to alter the shape of the ear, in the case of misshapen ears, or in the case of bat ears, surgery to pin them back. However, some seemingly minor ear deformities can be difficult, if not impossible, to address surgically. Even if surgery is likely to be successful, it is usually delayed until the age of five at the earliest, because before this the cartilage framework of the ear is too soft and floppy to hold sutures. Surgery has its disadvantages and complications too. Young children normally require a general anaesthetic, and bandages must usually be worn for a period of between seven and ten days afterwards. To avoid the ear kinking unfavourably on the pillow at night, a headband is best worn whilst sleeping for another six weeks or so.

Devices are known for holding back protruding ears, particularly in adults. One such device is attached between the ear and the head to hold the ear closer to the head. Another comprises a clip which is attached to the helix of the ear and to the wearer's hair to hold the ear closer to the head. These devices are designed to provide temporary correction only whilst they are worn and are effective only in simply holding the ear closer to the head.

The present invention provides an ear splint which can be used to correct a wider range of deformities and which can be used to hold the ear in a desired shape or position whilst the cartilage of the ear is hardening so as to effect a permanent correction.

According to a first aspect of the invention, there is provided an ear splint which can be formed into a desired shape and fitted to the auricle of the ear to assist in holding the ear in a desired position and/or shape.

According to another aspect of the invention there is provided an ear splint as detailed above in combination with protector means for fitting around the ear for protecting the ear from pressure from the splint when the head is laid down on the ear.

According to a further aspect of the invention there is provided a method of holding an ear in a desired shape and/or position in which an ear splint is formed into a desired shape and fitted to the auricle of the ear.

According to a yet further aspect of the invention there is provided a method of effecting a permanent re-moulding of the shape and/or position of an ear in which an ear splint as detailed above is fitted to the ear to hold the ear in the desired shape and/or position whilst the cartilage of the ear is hardening.

Other features of the invention will be apparent from the following description and from the subsidiary claims of the specification.

The invention will now be further described, merely by way of example, with reference to the accompanying drawings, in which:-

Figure 1 shows the various parts of an ear and the terminology used to describe them;

Figures 2A and 2B show a longitudinal and lateral cross-section respectively of an embodiment of an ear splint according to a first aspect of the invention, the longitudinal cross-section being shown in place in the ear;

Figure 3 shows an ear splint such as that shown in Figure 2 in situ in the ear of a baby; and

Figures 4A, 4B and 4C show three versions of protector means which may be used in combination with the ear splint.

Figure 1 shows a side view of the external ear or auricle. The various parts of the ear are labelled as described below.

pinna or auricle	the external ear
helix (or helical rim)	the curved, prominent rim of the ear, which extends around its periphery
antihelix	a curved, prominent ridge, parallel with and anterior to the posterior part of the helix. It divides above into two crura, between which is a depressed triangular fossa.
scaphoid fossa	the narrow curved depression between the helix and the antihelix
concha (of the auricle)	a deep capacious cavity partly encircled by the antihelix. The concha is incompletely divided into two by the crus or anterior end of the helix. Extending from the concha is the external acoustic or auditory meatus.
tragus	a small curved flap below the crus (or anterior end) of the helix, and in front of the concha, which partly overlaps the orifice of the external auditory meatus.
antitragus	a small tubercle opposite the tragus, at the lower end of the antihelix
lobule	the ear lobe
root of the helix	the anterior end, or crus, of the helix.

There are a number of deformities of the external ear which are apparent at birth, or in early infancy. Abnormal kinks, folds, bulges and ridges in the helix, scaphoid fossa or concha can occur. When the pinna or auricle extends more laterally from the head than is normal, the ears are said to be prominent or bat ears.

Figures 2A and 2B show an embodiment of an ear splint which comprises a body portion in the form of a wire 1. A sleeve or coating 2 formed of a dermatologically acceptable material is provided over the wire 1. The wire 1 can be formed into a desired shape and is preferably formed of a material that is sufficiently malleable to be shaped by finger pressure yet is sufficiently stiff to retain its shape when fitted to the ear and be effective in holding the ear to the desired shape. The splint can be bent in all directions so it can be formed into the desired three dimensional shape to fit the auricle of the ear and hold the ear in the desired shape and/or position.

The sleeve or coating 2 is preferably formed of a material which is relatively soft and so the splint is comfortable when fitted to the ear.

With the type of splint shown in Figure 2, a splint of the appropriate length and thickness is selected, bent to the appropriate shape and then fitted into the scaphoid fossa of the abnormal ear so as to hold the ear in the desired curved shape. The ear is then taped back against the side of the head (see Figure 3). The splint thus maintains the proper contours of the ear whilst pressure applied by the tape upon the splint within the ear acts to correct the tendency to prominence.

Depending on the circumstances and shape of the ear, the splint may be held in place simply by its location in the ear as described above. However, it is preferably secured in place by means of one or more strips of adhesive tape 3, as shown in Figure 3, which attach it to the helix of the ear and, as mentioned above, a strip of adhesive tape 4 is then used to hold the ear against the side of the head. The adhesive tape 3 and 4 is preferably transparent or flesh coloured.

The wire splint may be pre-formed in a curved shape so as to approximate to the typical shape of the scaphoid fossa of the ear so only minor adjustments are required to fit it to a specific ear.

The ear splint described above can be used to correct simple deformities and pin back prominent ears at a much earlier age than surgery permits. As described, the splint is fitted to the ear, nestling in a gully just within the helix or rim of the ear. Being of a soft and pliable construction, the splint is easily moulded with finger pressure to fit each individual ear. The whole ear is then taped to the side of the head to make it less prominent. Not only does the splint pin back the ear, it also emphasises the antihelix, and the helical rim that many prominent ears lack, and presses out any abnormal kinks and bends in the helix and/or scaphoid fossa to give a smooth, round contour. As the cartilage hardens whilst the splint is in place, a permanent correction is effected thus avoiding the need for surgery later in life.

The splint may also be used to re-shape ears without a helix (which is common with bat ears) by positioning the splint on the ear, rolling the periphery of the ear over the splint so as to form a helix and fastening in position with adhesive tape. The splint may also be used within the concha or on other areas of the ear, to re-shape the relevant area.

The splint works for the very reason that surgery at birth does not - the cartilage in the ear of the newborn child is extremely soft and malleable. The ear cartilage becomes firmer within a few days of birth and then gradually hardens towards its adult state over a period of several years. If a splint is applied to the ear whilst it is still malleable, it is possible to change the shape of the ear permanently and dramatically. In the newborn child a splint may need to be applied for only a few weeks to achieve such a correction. The older the infant, the longer splintage must be maintained to achieve the desired effect. This is particularly so in the case of prominent ears. Although the majority of prominent ears are obvious at birth, in a

number of children, prominence does not develop until they are several months old. The splint is effective in these older babies too, provided splintage can be begun within several months of birth.

The ear splint described above may be used in combination with protector means 5 which is fitted around the ear to protect the delicate skin of the ear from pressure from the splint when the head is laid on the ear, e.g. when the child is sleeping or resting.

The protector means provides a cushion around the ear and may be formed of a plastics foam material or other soft material. The protector means 5 may be formed in a variety of shapes, as illustrated by Figures 4A, B and C, to fit around the ear on the side of the head. As shown in the Figures, the protector means is preferably provided with perforations 6 for increasing air flow to the areas of skin against which it lies and to reduce the area of foam contact with the skin. The protector means 5 may, if necessary, be held in place by a headband or hat.

The body portion or wire core of the ear splint shown in Figure 2 is preferably formed of metal. Suitable metals include: zinc coated mild steel, titanium, stainless steel and aluminium.

The sleeve or coating 2 may be fitted over the wire core or may be formed thereon. Suitable materials for the sleeve or coating 2 include: polymerised rubber, a plastics foam known as Plastazote (Trade Mark) and other slow recovery foams, silicone foam, polyvinyl foam, polyvinylchloride foam and plastics materials, e.g. a gel based plastics material. The sleeve or coating 2 may be made flesh coloured. A range of colours may be provided to match different skin shades.

The foam and/or plastics materials used are preferably of medical grade and the adhesive tape used is preferably hypoallergenic.

The sleeve or coating 2 preferably completely encloses the wire core 1 so as to protect the core from corrosion and to prevent contact between the core and the ear. However, it will be appreciated that

only those parts of the external surface of the ear splint which, in use, contact the ear need be formed of or provided with a dermatologically acceptable coating 2.

Each end of the wire 1 is preferably terminated in a loop (not shown) so as to prevent the ends of the wire from cutting or eroding through the external sheath.

The embodiment of the ear splint described above has an elongate form with a substantially uniform width along its length as shown in Figure 2. The length and diameter of the splint required will depend on the shape and size of the ear to which it is to be fitted. However, splints with lengths in the range 2 cm to 10 cm, and more usually in the range 4 cm to 9 cm, will suit the majority of applications. Similarly, splints with a lateral thickness or diameter in the range 2 mm to 15 mm and more usually in the range 3 mm to 7 mm, will suit the majority of applications. The wire core is typically 1 to 3 mm in diameter, the remainder of the thickness of the splint comprising the sleeve or coating 2. A splint having a length of approximately 6 cm and a diameter of approximately 4 mm has been found to fit the ears of the majority of newborn babies.

The splint may also be provided in longer lengths so it can be cut to the desired length. Protector caps would then, if necessary, be fitted over the cut ends.

An alternative form of splint (not shown) may comprise heat malleable plastics material which can be formed to the desired shape when heated but which regains its stiffness on cooling. If the plastics material used is dermatologically acceptable no additional sleeve or coating would be required.

To assist further in securing the ear splint within the ear, a contact adhesive may be provided on at least part of the external surface of the splint. In some cases this may preclude the need to use adhesive tape as described above, but in other cases adhesive tape may be used in addition.

It will be appreciated that the use of the ear splint described above is extremely simple and inexpensive. An ear splint may be applied by a doctor or surgeon but the technique is so simple that parents may be able to install a splint on their own children.

Although the invention has been described above by reference to an ear splint of elongate form, other forms of ear splint may also be provided for fitting within the scaphoid fossa or for application to other areas of the ear. For example, a splint having a shape which conforms to the usual contours of the entire surface of the auricle, i.e. not only to the shape of the scaphoid fossa but also to the antihelix and/or to the upper part of the concha. Such a splint may be easier for the layman to fit than the elongate form of splint described above. In each case, the splint comprises a material which can be formed to a desired shape to fit the relevant part of the ear and hold the ear in a desired shape and/or position.

As mentioned above, the ear splint is preferably applied to the ear within a few days of birth whilst the cartilage is still soft. A permanent correction can then be achieved within a few weeks, e.g. 3 weeks if the splint is worn substantially continuously during this period after which the splint can be removed. If the splint is fitted later, it needs to be worn for a longer period to effect a permanent correction. For example, a splint fitted a month after birth may need to be worn for 2 months and a splint fitted 3 months after birth may need to be worn for 3 months. The splint is preferably fitted within 6 months of birth otherwise it may be necessary to soften the cartilage of the ear as described below to enable a permanent correction to be effected.

Ear splints such as those described above may also be used for correcting the shape or position of adult ears by the use of a topical chemotherapeutic agent to reduce the rigidity of the ear cartilage prior to or whilst the splint is fitted to the ear.

Suitable chemotherapeutic agents for cartilage softening include: preparations comprising oestrogen and preparations comprising chymopapain

CLAIMS

1. An ear splint which can be formed into a desired shape and fitted to the auricle of the ear to assist in holding the ear in a desired position and/or shape.
2. An ear splint as claimed in Claim 1 which is sufficiently malleable to allow it to be formed into a desired shape yet sufficiently stiff so as to retain its shape when fitted to the ear.
3. An ear splint as claimed in Claim 2 which is sufficiently malleable to be formed into a desired shape by finger pressure.
4. An ear splint as claimed in Claims 1, 2 or 3 comprising a body portion formed of metal.
5. An ear splint as claimed in Claim 4 in which the metal is selected from the group consisting of: zinc coated mild steel, titanium, stainless steel and aluminium.
6. An ear splint as claimed in any preceding claim, in which the external surfaces which, in use, contact the ear comprise a dermatologically acceptable material.
7. An ear splint as claimed in Claim 6 in which the said external surfaces comprise a relatively soft material so the splint is comfortable when fitted to the ear.
8. An ear splint as claimed in Claim 7 in which the said external surfaces are formed of a material selected from the group consisting of: polymerised rubber, silicone foam, polyvinyl foam, polyvinylchloride foam, a plastics material and a gel based plastics material.
9. An ear splint as claimed in any preceding claim having an elongate form.

10. An ear splint as claimed in Claim 9 having a length in the range 2 cm to 10 cm and preferably in the range 4 cm to 9 cm.
11. An ear splint as claimed in Claim 9 or 10 having a substantially uniform width along its length in the range 2 mm to 15 mm and preferably in the range 3 mm to 7 mm.
12. An ear splint as claimed in Claims 4, 6 and 9 comprising a metal body portion in the form of a wire core, the wire core being enclosed within an outer covering of a dermatologically acceptable material.
13. An ear splint as claimed in Claim 12 in which the outer covering comprises a tube fitted over the wire core.
14. An ear splint as claimed in Claim 12 in which the outer covering comprises a coating or sheath formed on the wire core.
15. An ear splint as claimed in any of Claims 9 to 14 which is pre-formed in a curved shape so as to approximate to the typical shape of the scaphoid fossa of the ear.
16. An ear splint as claimed in any preceding Claim comprising attachment means for assisting in securing the splint to the ear.
17. An ear splint as claimed in Claim 16 in which the attachment means comprises a contact adhesive applied to at least part of the external surface of the splint.
18. An ear splint as claimed in Claim 16 or 17 in which the attachment means comprises a plurality of adhesive strips for securing the splint to the ear.
19. An ear splint substantially as hereinbefore described with reference to Figures 2 and 3 of the accompanying drawings.

20. An ear splint as claimed in any preceding Claim in combination with protector means for fitting around the ear for protecting the ear from pressure from the splint when the head is laid down on the ear.
21. An ear splint as claimed in Claim 20 in which the protector means is adapted to provide a cushion between the ear and whatever it is laid upon.
22. An ear splint as claimed in Claim 21 in which the protector means comprises a plastics foam material.
23. An ear splint as claimed in Claims 20, 21 or 23 in which the protector means is perforated in order to increase airflow to the areas of skin against which it lies in use.
24. An ear splint as claimed in any of Claims 1 to 19 in combination with protector means substantially as hereinbefore described with reference to Figure 4.
25. A method of holding an ear in a desired shape and/or position in which an ear splint as claimed in any preceding Claim is formed into a desired shape and fitted to the auricle of the ear.
26. A method as claimed in Claim 25 in which adhesive tape is used to assist in holding the ear splint in place on the ear.
27. A method as claimed in Claim 25 or 26 in which after the splint has been positioned in the ear, the ear is held against the side of the head by adhesive tape or a headband.
28. A method as claimed in Claim 25, 26 or 27 in which the ear splint is fitted to the ear whilst the cartilage of the ear is still malleable, preferably within six months of birth and most preferably within three months of birth.

29. A method as claimed in Claim 25, 26 or 27 in which a topical chemotherapeutic agent is applied to the ear to reduce the rigidity of the cartilage thereof prior to or whilst the ear splint is fitted to the ear.
30. A method as claimed in Claim 29 in which the chemotherapeutic agent is selected from the group consisting of: a preparation comprising oestrogen and a preparation comprising chymopapain.
31. A method as claimed in any of Claims 25 to 30 in which protector means are fitted around the ear to protect the ear from pressure from the splint when the head is laid down on the ear.
32. A method of holding an ear in a desired shape or position using an ear splint as claimed in any of Claims 1 to 24.
33. A method of holding an ear in a desired shape or position substantially as hereinbefore described.
34. A method of effecting a permanent re-moulding of the shape and/or position of an ear in which an ear splint is fitted to the ear to hold the ear in the desired shape and/or position whilst the cartilage of the ear is hardening.
35. A method of effecting a permanent re-moulding of the shape and/or position of an ear substantially as hereinbefore described.



Application No: GB 9517764.8
Claims searched: 1 to 35

Examiner: Mr S.J.Pilling
Date of search: 17 June 1996

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:
UK CI (Ed.O): A5R (RFB, REYA, REYX)
Int CI (Ed.6): A61B 17/00, 19/00, A61F 11/00, 11/06, 11/08, 11/10, 11/14
Other: ONLINE: WPI, DIALOG/MEDICINE, CLAIMS

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	British Journal of Plastic Surgery, Vol. 47, No. 8, December 1994, S T Tan et al, " <i>A splint for correction of congenital ear deformities</i> ", pages 575-578, particularly the " <i>Materials and method</i> ", Figures 1, 2B, 6B and the final paragraph of the " <i>Discussion</i> " on page 578.	1-19,25-30,32-35
X	British Journal of Plastic Surgery, Vol. 47, No. 8, 1994 (UK), M Noguchi et al, " <i>Simple surgical correction of Stahl's ear</i> ", pages 570-572, particularly the " <i>Surgical technique</i> " and Figure 1D.	1,6,7,9-11,15-18,25-28,32-35
X	British Journal of Plastic Surgery, Vol. 46, No. 7, 1993, T Yotsuyanagi, " <i>Compressive plastic splint for postoperative management of the ear</i> ", pages 622-623, particularly the " <i>Technique</i> " and Figures 1 to 2.	1-3,6-11,15,25,32,33,35
X	Journal of Oral and Maxillofacial Surgery, Vol. 50, No. 8, August 1992, W J Starck and S I Kaltman, " <i>Current concepts in the surgical management of traumatic auricular hematoma</i> ", pages 800-802,	1-3,6,7,9-11,15,16,20,21,25,31-33,35
X	Journal of Athletic Training, Vol. 27, No. 3, 1992, T M Keating and J Mason, " <i>A simple splint for wrestler's ear</i> ", pages 273-274	1-3,6,7,9-11,15,16,20-23,25,27,31-33,35

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.

& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.



Application No: GB 9517764.8
Claims searched: 1 to 35

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Category	Identity of document and relevant passage	Relevant to claims
X	Laryngologie, Rhinologie, Otologie, Vol. 69, No. 11, 1990, M Bernal-Sprekelsen and F J Krummel " <i>Die konservative Korrektur angeborener Formanomalien der Ohrmuschel</i> ", pages 581-585, particularly the abstract and Figure 4	1-3,6,7,9-11,15-18,25-28,32-35
X	Journal of Laryngology and Otology, Vol. 103, No. 12, December 1989, S S Nahl et al, " <i>Treatment of auricular haematoma by silicone rubber splints</i> ", pages 1146-1149, particularly the " <i>Methods</i> " and Figure 5	1-3,6-11,15,16,25,32,33,35
X	Journal of Laryngology and Otology, Vol. 101, No. 9, September 1987 (England), B J G Bingham and E B Chevetton, " <i>Silicone ear splints in the management of acute haematoma auris</i> ", pages 889-891, particularly the " <i>Hearing mould splint method</i> " and Figure 1	1-3,6-11,15,16,25,27,32,33,35
X	Pediatrics, Vol. 78, No. 3, September 1986, F E Brown et al, " <i>Correction of congenital auricular deformities by splinting in the neonatal period</i> ", pages 406-411, particularly the " <i>Materials and methods</i> ", Figures 5 and 6.	1-3,6,7,9-11,15-19,25-29,32-35
X	British Journal of Plastic Surgery, Vol. 35, No. 2, April 1982 (Scotland), N Kurozumi et al, " <i>Non-surgical correction of a congenital lop ear deformity by splinting with Reston foam</i> ", pages 181-182	1-3,6-8,10,11,16,17,25,28,32-35
X	Laryngoscope, Vol 90, No. 5, 1980, W H Gernon, " <i>The care and management of acute hematoma of the external ear</i> ", pages 881-885, particularly the " <i>Technique</i> " and the figures	1-3,6,7,9-11,15-17,25,32,33

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.
& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.